

MAR 31 2006

510(k) Summary

NAME OF SPONSOR: **DePuy Orthopaedics, Inc.**
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

MANUFACTURER: **DePuy Orthopaedics, Inc.**
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(K) CONTACT: **Natalie S Heck**
Manager, Regulatory Affairs
Phone: (574) 372-7469
Fax: (574) 371-4987

TRADE NAME: **Agility™ LP Total Ankle Prosthesis**

COMMON NAME: Ankle Prosthesis

CLASSIFICATION: **Class II** Ankle Joint metal/polymer semi-constrained
cemented prosthesis per 21 CFR §888.3110

DEVICE PRODUCT CODE: 87 HSN

**SUBSTANTIALLY EQUIVALENT
DEVICES:** **DePuy Agility™ Total Ankle Prosthesis**
(formerly cleared as Alvine Ankle)

DEVICE DESCRIPTION:

The Agility™ LP Total Ankle Prosthesis proposed in this submission are a line extension to the Agility™ Total Ankle system components (cleared as DePuy Alvine Total Ankle Prosthesis under K920802, December 17, 1992). The Agility LP Ankle is a modular ankle prosthesis that is comprised of a tibial tray, a polyethylene tibial insert and a talar component.

510(k) Summary (cont.)

INTENDED USE AND INDICATIONS:

The Agility™ LP Total Ankle Prosthesis components, as part of the DePuy Agility™ Total Ankle Prosthesis System are intended for use in patients with end stage ankle disorders as an alternative to ankle fusions.

Total ankle arthroplasty is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post traumatic or degenerative arthritis in elderly individuals with reduced activity levels.

CAUTION: The Agility Ankle Prosthesis is intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the Agility LP Ankle Prosthesis is demonstrated by its similarity in indications for use, design, materials, sterilization and packaging to the Agility Ankle cleared in K920802 (formerly called the Alvine Ankle).



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
c/o Ms. Natalie S. Heck
Manager, Regulatory Affairs
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K053569

Trade/Device Name: Agility™ LP Total Ankle Prosthesis
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: February 27, 2006
Received: March 1, 2006

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

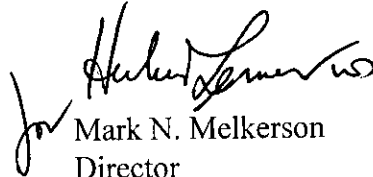
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Natalie S. Heck

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a printed name. To the left of the signature is a small, stylized handwritten mark that looks like "for".

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053569

Indications for Use

510(k) Number (if known): _____

Device Name: Agility™ LP Total Ankle Prosthesis

Indications for Use:

Total ankle arthroplasty is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post traumatic or degenerative arthritis in elderly individuals with reduced activity levels.

CAUTION: The Agility Ankle Prosthesis is intended for cemented use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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